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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,886	10/29/2003	Andrew B. Lederman	050508-1110	7813
24504 7590 09/25/2007 THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 100 GALLERIA PARKWAY, NW STE 1750 ATLANTA, GA 30339-5948			EXAMINER BACHMAN, LINDSEY MICHELE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 09/25/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/695,886	<b>Applicant(s)</b> LEDERMAN, ANDREW B.	
	<b>Examiner</b> Lindsey Bachman	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-14 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-14 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to Applicant's Request for Continued Examination filed on 21 August 2007.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The correct statement should read: "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3, 5-8, 10-14, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brunken (EP 0 615 726 A1).**

Claims 1 and 10: Brunken'726 discloses a needle with a curved cylindrical shaft (2, Figure 1) and a puncture tip (6) at one end of the curve (see Figure 1) of the shaft (2). The shaft has a front surface (8) and rear surface (10) that extend side by side along the length of the shaft. The shaft is marked at least partially with a visual indicator (page 2, lines 29-34). The rear surface is distal to the puncture tip (see Figure 1). Both the rear surface and front surface have visual indicators (see Figure 1 and page 2, lines 29-34).

Claims 2, 3, 4-7: Brunken'726 discloses that the front surface (8) includes a visual indicator of bare or untreated metal, which is a first color, and a rear surface (10), distal to the tip, that includes a visual indicator that is matte-finished or colored, which is a second color (page 2, lines 29-34).

Claim 8: Brunken'726 discloses that the entire front surface of the needle consists of bare or untreated metal (first color) and rear surface can be continuously matte-finished or colored (second color) (page 2, lines 29-34 and Figure 1).

Claim 11, 12, and 14: Brunken'726 discloses a surgical needle with a curved cylindrical shaft (Figure 1) containing a puncture tip (6) and a shaft (2) extending from the tip (6) including a means for distinguishing between the front surface of the shaft (2) that is proximal to tip (6) and the rear surface of the shaft (10) that is distal to tip (6) (see Figure 1).

Claim 13: Brunken'726 discloses a shaft having a front surface (near tip 6) that includes a visual indicator of bare or untreated metal, which is a first color, and a rear

surface that includes a visual indicator that is matte-finished or colored, which is a second color (page 2, lines 29-34).

Claim 20: Brunken'726 discloses a method of making a suture needle that includes providing a suture needle (page 3, lines 5-9) and marking at least a portion of the needle with a visual indicator (page 3, lines 14-17). The portion must extend at least partially along a length of the needle. The inside curve of the needle is marked with a visual indicator (see Figure 1 and page 2, lines 29-34).

**Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsutani, et al. (US Patent 4,935,029).**

Matsutani'029 discloses a suture needle (Figure 16) that contains a shaft (7) having a front surface (I) and a rear surface (O) (see Figures 12-15) that extend side by side along at least a portion of the shaft (see band 4 in Figure 16). The portions are marked with a visual indicator (4) that can differentiate the front and rear portions of the shaft from one another (columns 10-11). The device also contains a puncture tip at its distal end (see Figure 16).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brunken'726, as applied to Claim 1, in view of Anis (US Patent 5,352,233).**

Brunken'726 teaches the limitations of Claim 9, except a mechanism for determining the needle's angle of orientation.

Anis'233 teaches a medical device in which a visual indicator on the device aids in determining the angle of orientation of the instrument (column 3, lines 58-68) in order to aid the surgeon in orienting the device (column 3, lines 30-36). Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a visual indicator to aid in determining the angle of orientation of the device.

### ***Response to Arguments***

Applicant's arguments filed 21 August 2007 have been fully considered but they are not persuasive.

Applicant argues that Brunken does not teach a suture needle with two surfaces that extend side-by-side along at least a portion of the shaft. This is not convincing because the front and rear portions disclosed clearly extend side by side along the

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entire length of the shaft (see Figure 1). Regarding Claim 20, Applicant argues that the claim amendments clarify between the inside and outside of the curve. This is not persuasive because Applicant only defines that the front surface is on the inside curve of the needle. Since Applicant does not define the rear surface, it is reasonable to interpret this to mean that the front surface is also on the outside curve, and the rear surface is behind (or towards the back near where an eyelet for suture material would typically be located) the front surface.

Applicant argues that it would not be obvious to extend the visual indicator disclosed by Matsutani along the length of the shaft of the needle. This argument may be persuasive, however, the limitation of extending a visual indicator along the entire length of the needle is not claimed by Applicant in Claims 1 or 11. Further, element 4 does serve to differentiate between the inner and outer surfaces of the needle, regardless of where they are located along the shaft. Applicant argues that the rear surface is outside the curve of the shaft, not necessarily away from the needle. This is not persuasive because the outer surface on the needle disclosed by Matsutani is both on the outside curve AND also extends to a point away from the tip of the needle.

### ***Conclusion***

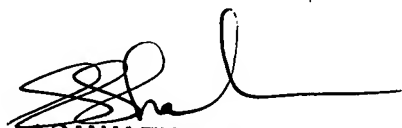
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lb

  
LOAN H. THANH  
PRIMARY EXAMINER